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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/470,697 | 12/23/1999 | WALID NAJIB ABOUL-HOSN | AMED056 | 6483 |

7590 07/29/2003

A-MED SYSTEMS INC
INTELLECTUAL PROPERTY
2491 BOATMAN AVENUE
WEST SACRAMENTO, CA 95691

EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 07/29/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/470,697 | ABOUL-HOSN ET AL. |
| Examiner | Art Unit | |
| Patricia M Bianco | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,6 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,6 and 8-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 02 May 2003 is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input checked="" type="checkbox"/> Other: <i>Final Rejection</i> . |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed May 02, 2003 has been entered.

The substitute specification has been approved and entered.

The changes to the drawings filed May 02, 2003 have been approved and entered. New formal drawings, including the changes submitted, are required upon allowance.

Claims 2-5, 7, and 12-16 have been cancelled.

Claims 1, 6 and 8-11 have been amended and remain pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, & 8-11 remain rejected under 35 U.S.C. 102(e) as being anticipated by Aboul-Hosn (6,083,260). Aboul-Hosn discloses a cannula system for transporting

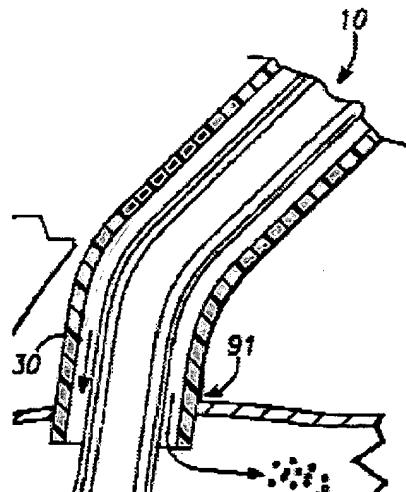
body fluids into and/or out of a vessel or heart chamber. The device comprises an outer cannula (30) having an inner cannula (20) disposed within its lumen. The outer cannula and inner cannula both have individual lumens that are seen to be equivalent to "the first and second fluid flow paths" of applicant's invention. The outer cannula has an opening just proximal to the balloon, which is seen to be equivalent to Applicant's claimed "port," to allow fluid to exit its lumen or flow path. The inner cannula has a plurality of openings (27) or ports in communication with its inner lumen, or second flow path. As shown in figures 14-19, the distal end of the outer tube has a curved portion. Since Aboul-Hosn teaches that the inner cannula is slidable through the outer cannula, the inner cannula will be inherently directed by the curved portion of the outer tube beyond the distal end of the outer cannula. Aboul-Hosn also discloses that the inner cannula may have a permanent bend formed in an angle of 10 to 120 degrees (col. 7, lines 30-34). As the pictures show, the curved portion of the outer cannula has the same angle of the inner tube, and therefore, the limitations of claims 9-11 have been met. Aboul-Hosn also discloses a reverse flow pump (50) that is connected to the outer cannula (30) (see col. 15, lines 9-35). The limitation of claim 6 that the proximal ends are "adapted" and configured to be coupled to a pump is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. However, Aboul-Hosn teaches that the outer and inner cannulae are disclosed to be arranged to assist the delivery of blood to and from the pump and therefore is seen to be configured to be coupled to a pump. With respect to the limitations of claim 6 requiring the outer and inner cannulae

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to be extending outside an incision, these limitations are seen to be an intended use recitation for the device and have not been given patentable weight.

Response to Arguments

3. Applicant's arguments filed May 02, 2003 have been fully considered but they are not persuasive. Applicant's argument is that Aboul-Hosn does not teach of an inner cannula slidable within an outer cannula, wherein the outer cannula includes a curved portion that directs the passage of the inner cannula beyond the distal end of the outer cannula. The examiner respectfully disagrees. As shown in figures, for example see figure 14 below, the distal end of the outer tube has a curved portion and shows the inner cannula slidable through the outer cannula. This curved portion inherently directs the inner cannula out of the outer tube and beyond the distal end of the outer cannula.



Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

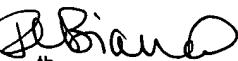
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb 
July 25th, 2003